

December 8, 1997

R974625

510(K) SUMMARY

Submitted by:

MAR - 4 1998

Ralph H. Larsen
Manager, Regulatory Affairs
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, Texas 76134-2099
(817) 551-4702 (Phone)
(817) 551-4630 (Fax)

Device Name:

Common Name: Contact Lens Cleaning Solution

Proprietary Name: OPTI-FREE® SUPRACLENS® Daily Protein Remover

Indications for Use:

OPTI-FREE® SUPRACLENS® Daily Protein Remover is indicated for use with daily wear and extended wear soft (hydrophilic) contact lens to simultaneously enzymatically clean them while they are being disinfected (soaked) in Alcon Multi-Purpose Disinfecting Solution ID 90746, OPTI-FREE Rinsing, Disinfection and Storage Solution, OPTI-FREE *EXPRESS* Multi-Purpose Solution or OPTI-ONE Multi-Purpose Solution. **Use as recommended by your eye care practitioner.**

Description:

OPTI-FREE® SUPRACLENS® Daily Protein Remover is a sterile, preservative-free aqueous suspension, containing pancreatin as the active cleaning agent.

Substantial Equivalence:

This product is substantially equivalent, in terms of its actions and indications for use, to Alcon OPTI-FREE® SUPRACLENS® Daily Protein Remover. Only the labeling is being changed to allow Alcon Multi-Purpose Disinfecting Solution ID 90746 to be used as a diluent. This product was previously approved for marketing under Premarket Approval Application P820001/S18. OPTI-FREE® SUPRACLENS® Daily Protein Remover meets the guidelines set forth in FDA's May 1, 1997 Guidance for Industry; Premarket Notification (510(k) Guidance Document for Contact Lens Care Products.

Safety and Effectiveness:

A. Non-Clinical Data

Microbiological Studies

The product was evaluated for microbiological safety and effectiveness using the FDA Guidelines for contact lens solutions. During simultaneous enzymatic cleaning and disinfection, the formulation meets the Stand-Alone criteria for disinfection of contact lens against bacteria, yeast and mold.

Preclinical

Preclinical toxicology tests have been conducted to substantiate the safety of the product for use in cleaning, of all soft (hydrophilic) contact lens (Group I, II, III, and IV). The studies include: (1) cytotoxicity (agar overlay); (2) ocular safety (irritation) evaluations.

Compatibility/Cleaning Efficacy

Studies were conducted to determine product compatibility with soft contact lenses and its ability to clean laboratory deposited lenses. The studies demonstrated the compatibility and cleaning efficacy of the OPTI-FREE® SUPRACLENS® Daily Protein Remover/Alcon Multi-Purpose Disinfecting Solution ID 90746 regimen.

B. Clinical

A study was conducted to clinically evaluate the safety and efficacy of OPTI-FREE® SUPRACLENS® Daily Protein Remover/Alcon Multi-Purpose Disinfecting Solution ID 90746 regimen for cleaning, rinsing, and disinfection of all soft (hydrophilic) contact lenses (65 patients/130 eyes - 3 months). This clinical study demonstrated the OPTI-FREE® SUPRACLENS® Daily Protein Remover/Alcon Multi-Purpose Disinfecting Solution ID 90746 regimen is safe and effective for the daily simultaneous enzymatic cleaning and disinfection of soft (hydrophilic) contact lenses.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 4 1998

Mr. Ralph H. Larsen
Manager, Regulatory Affairs
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, Texas 76134-2099

Re: K974625
Trade Name: OPTI-FREE ® SUPRACLENS ® Daily Protein Remover
Regulatory Class: II
Product Code: 86 LPN
Dated: December 8, 1997
Received: December 11, 1997

Dear Mr. Larsen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in cursive script that reads "A. Ralph Rosenthal".

A. Ralph Rosenthal, M.D.

Director

Division of Ophthalmic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K974625

Device Name: OPTI-FREE® SUPRACLENS® Daily Protein Remover

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. Smith
(Division Sign-Off)

Division of Ophthalmic Devices

510(k) Number K974625

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X